Original Article

Prevalence of diabetic retinopathy in India: The All India Ophthalmological Society Diabetic Retinopathy Eye Screening Study 2014

Salil S Gadkari, Quresh B Maskati, Barun Kumar Nayak

Aim: The aim of this study is to ascertain the prevalence of diabetic retinopathy (DR) in diabetic patients across the nation and attempt to establish history-based risk factors. **Materials and Methods:** A cross-sectional study of diabetic patients was conducted as an initiative of the All India Ophthalmological Society from 14th November to 21st November 2014. Known diabetics were evaluated voluntarily by members of the society at 194 centers using a structured protocol provided by the society for examination. The results were evaluated to ascertain the prevalence of DR in the population studied and to establish relation with gender, age, and history-based risk factors such as duration of diabetes, insulin use, and other end-organ disease using the Chi-square test. **Results:** A total of 6218 known diabetics were screened. Totally, 5130 data entry forms were considered suitable for further evaluation. About 61.2% were males, 88.6% were between 40 and 80 years of age, almost two-thirds of the patients were from the west and south zones, and over half had diabetes more than 5 years. The data set was predominantly urban 84.7% and 46.1% had no family history. DR prevalence in the entire data set was 21.7%. Prevalence was more in males (P = 0.007), diabetics more than 5 years (P = 0.001), those above 40 years (P = 0.01), insulin users (P = 0.001), and history of vascular accidents (P = 0.0014). Significantly 22.18% of patients detected with DR had a vision of 6/18 or better in the worse eye. **Conclusion:** The study reiterated the findings of earlier regional studies on a pan Indian scale and put data in perspective.

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India is set to emerge as the diabetic capital of the world. According to the WHO, 31.7 million people were affected by diabetes mellitus (DM) in India in the year 2000. This figure is estimated to rise to 79.4 million by 2030, the largest number in any nation in the world. Almost two-third of all Type 2 and almost all Type 1 diabetics are expected to develop diabetic retinopathy (DR) over a period of time.[1-3] With the intention of ascertaining the magnitude of the problem and to generate awareness, the All India Ophthalmological Society (AIOS), in 2014, took an initiative to detect the presence of DR among persons with diabetes in eye clinics across the length and breadth of the country. The exercise marked the first pan India initiative, outside the government, to take the first steps against the problem of DR blindness. While the purpose of the study was to assess prevalence and explore risk factors for developing DR among known diabetics, it also sought to identify lacunae in the current process of case detection to improve future screening programs.

Materials and Methods

A nationwide population-based cross-sectional study of diabetic patients was conducted as an initiative of the AIOS from 14th November to 21 November 2014. Members of the society at 194 centers volunteered to participate. A structured protocol provided by the society was used for documenting patient assessments. Ethics committee approval was sought and obtained from Aditya Jyot Eye Hospital Ethics Committee, Mumbai. All participants had to sign an MOU agreeing to comply with the protocol during examination of the patients. Consent to use personal data was obtained from all patients. The findings were recorded in form 1 [Fig. 1]. Diabetes was self-reported. All the questions for eliciting history were administered to the patient in his/her own language. Standard techniques and equipment were used for clinical examination; retinal evaluation was done using a direct/indirect ophthalmoscope or 90D lens on slit lamp or by fundus photography. Grading of the retinopathy and the presence of macular edema were kept outside the purview of the present study: Confining information collected to the presence or absence of "any DR." The prevalence of DR in the study population was estimated, and the Chi-square test was used to explore associations with gender, age duration of diabetes, insulin use, and other end-organ disease. Prevalence of DR was also calculated for different levels of vision in the eye with poorer vision.

Results

Of 6218 patients screened across 194 centers, 5130 data entry forms were considered suitable for further evaluation.

Head Office, All India Ophthalmological Society, Near Deepak Memorial Hospital, Karkardooma, New Delhi, India

Correspondence to: Dr. Salil S Gadkari, All India Ophthalmological Society, 8A, Karkardooma Institutional Area, Near Deepak Memorial Hospital, Karkardooma, New Delhi - 110 092, India. E-mail: drgadkari@gmail.com

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Identification Data	Response Categories	
Name of Respondent		Gender: Male =1, Female = 2.
Person Unique ID No	☐☐☐ ☐☐☐	
Age	_____ (in complete years)	
Address		
Phone / Email ID		
Date of Examination	(dd / mm /yyyy) ____/____/_____	
Duration of Diabetes Since Detection	(in years and months)	
Family History (If yes, put P or S or both in box) Parents / Siblings (P/S)	☐ Yes P/S or PS, No 2,Don't know 3	
Are you on any Medication for Diabetes (Insulin : I / Oral : O) (if yes, put I or O in box)	☐	Duration of Medication _____
Nature of Medication	☐ 1. Allopathic ☐ 2. AAYUSH System ☐ 3. Home remedies	
Do you have any other complication Of Diabetes? If yes, please specify.	1. Kidney 2. Heart 3. Stroke 4.Other 5. No Complication.	
Anthropometry	Height (cm) _____ Weight (Kg) _____	
Vitals	Blood Pressure (mmHg)	Blood Sugar (mg/dl)_____ Last Meal Taken _____
Presenting Visual Acuity	Right Eye _____	Left Eye _____
Lens (Cataract :1, Normal :2, Aphakia : 3, Pseudophakia : 4)	☐	☐
Fundus Photograph after dilating pupils	☐	☐
(Yes : 1, No : 2)		
IOP in mmHg	☐	☐
Presence of Diabetic Retinopathy 0 : No DR, 1. Mild NPDR, 2. Moderate NPDR, 3. Severe NPDR, 4. PDR, 99. Could not be Assessed (CNBA)	☐	☐
Diabetic Macular Edema Yes : 1, No : 2	☐	☐
Patient Referred to Higher Centre	1. DR 2. Cataract 3.Others Specify_____	
Other Ocular Disease	Right Eye	Left Eye
Name / Signature of Ophthalmologist & Date		

I consent to use of the information in this case sheet for research purposes

Signature of patient/thumb impression

Figure 1: Form 1 was used to enter the data of all patients screened

Among these, 61.2% were males. About 88.6% of those screened were between 40 and 80 years of age. The west and south zones accounted for almost two-thirds of the patients evaluated [Fig. 2 and Table 1], and over half had diabetes more than 5 years. The data set was predominantly urban 84.7% and close to half 46.1% had no family history. Nearly 94.4% of the patients were taking treatment under the allopathic system of medicine for their DM: 81.1% with oral hypoglycemic agents. The prevalence of DR in the entire data set was 21.7% (95% confidence interval [CI] 20.54–22.79). Prevalence was more in males (P = 0.007) (odds ratio [OR] 1.212, 95% CI 1.055–1.391), duration of diabetes more than 5 years (P = 0.001) (OR 3.318, 95% CI 2.85–3.863) [Fig. 3 and Table 2], above 40 years of age (P = 0.01) (OR 2.367, 95% CI 1.997–3.482) [Table 3], insulin users (P = 0.001), those with history of vascular accidents (P = 0.0014,) and diabetic nephropathy (P = 0.001) [Table 4]. Significantly, 22.18% of patients detected with DR had a vision of 6/18 or better in the eye with worse vision [Tables 5 and 6].

Discussion

Most screening programs are a trade-off between the information meticulously gleaned by painstakingly complying with the recommended gold standard and diluting the process just enough to still maintain acceptable levels of diagnostic accuracy while optimizing coverage.[4] This study estimated the magnitude of the problem and explored regional differences in prevalence. India is a subcontinent with variations in diet, lifestyle, and ethnicity. The level of health literacy and access to health care also varies across the country.

Over the past decades, many cross-sectional studies have been conducted to ascertain the prevalence of DR in the diabetic population in various regions of the country and world.

In India, the previous studies to calculate prevalence were by Raman *et al*. (18.1%), Rema *et al*. (17.6%), Namperumalsamy *et al*. (10.6%), Narendran *et al*. (26.2%) and Dandona *et al*. (22.58%), and so on [Table 7].[5-10] Most of these studies were conducted in the southern states of the country. Few studies exist in the indexed literature to cover other parts of the country. All the published studies were conducted by a single agency in a relatively homogenous population over an extended data collection period often being reported by retina consultants. This ensured relatively strict adherence to the protocol and meticulous completion of the data collection sheet. Except for one study, most were restricted to tier 2 and tier 1 city.

Table 1: Zone-wise distribution of diabetic patients screened and the zone-wise prevalence

Zones	Total screened patients	Percentage of screened patients from each zone	Zone-wise prevalence
North	276	5.3	34.06
East	943	18.3	22.59
West	1646	31.9	21.75
Central	554	10.7	12.27
Northeast	106	2.1	14.15
South	1638	31.7	22.65

Table 2: Prevalence of diabetic retinopathy in relation to duration of diabetes mellitus

Duration of DM	Prevalence of DR
<6 months	9.23
6 months-5 years	15.12
>5 years	35.12

DM: Diabetes mellitus, DR: Diabetic retinopathy

Table 3: Age-wise distribution of the diabetic patients screened and the prevalence of diabetic retinopathy

Age in years	Diabetic retinopathy			Prevalence (%)
	Present	Absent	Total	
0-20	2	59	61	3.28
21-40	57	458	515	11.07
41-60	581	2079	2660	21.84
61-80	448	1341	1789	25.04
>80	13	43	56	23.21

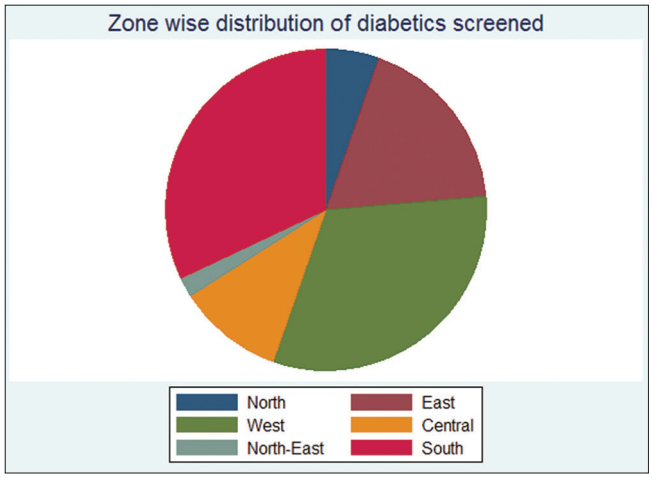

Figure 2: Pie chart showing zone-wise distribution of diabetics screened

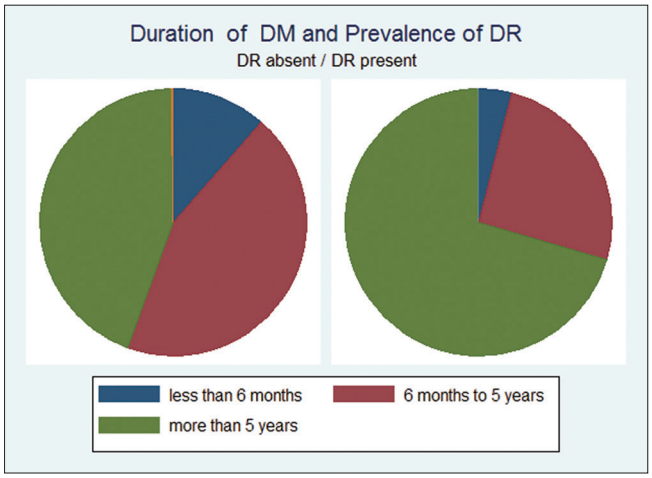

Figure 3: Pie chart showing duration of diabetes mellitus and prevalence of diabetic retinopathy

Table 4: Prevalence of diabetic retinopathy in patients with other end-organ disease

Relation to other end-organ disease	Prevalence (%)
Renal	42.86
Cardiac	29.34
Stroke	31.82
Others	22.47
No complications	21.06
Multiple	48.72

Table 5: Prevalence of diabetic retinopathy at different levels of visual acuity. The vision in the lesser seeing eye was considered for the purpose of evaluation

Visual acuity in lesser seeing eye	Prevalence (%)
6/6	11.17
6/9	19.41
6/12	22.80
6/18	25.21
6/24	27.32
6/36	31.13
6/60	25.68
<6/60	35.60
Hand movements or less	28.00

Table 6: Prevalence of diabetic retinopathy at visual acuity at 6/18 or better as compared to <6/18. The vision in the worse seeing eye was considered for the purpose of evaluation

Vision in worse seeing eye (BCVA)	DR			
	Present	Absent	Total	Prevalence
6/18 or better	628	2831	3459	22.18
<6/18	403	957	1360	42.11

DR: Diabetic retinopathy, BCVA: Best-corrected visual acuity

Uniqueness of the AIOS study was its execution by multiple centers working independently to implement the protocol created by the AIOS. Case detection was predominantly performed by the comprehensive ophthalmologist, not necessarily retina consultants. The data collection was also performed during a much shorter period, hence requiring a larger number of patients to be assessed during each session. The program incorporated many principles elucidated in the guidelines issued by Vision 2020 India and Aravind eye care system in their publication in 2008.[3] The prevalence in the AIOS study was 21.27% with a range of 12.27% in the central zone and 34.06% in the north zone [Fig. 4].

Studies performed across the globe reported varying rates of prevalence such as Lian *et al*. (39%) in Hong Kong, Rodriguez-Poncelas *et al*. (12.3%) in Spain, Dawkins *et al*. (18.6%) in Timor-Leste, Huang *et al*. (33.9%) in Singapore, Giloyan *et al*. (36.2%) in Armenia, Hajar *et al*. (27.8%) in Saudi Arabia, and Dutra Medeiros *et al*. (16.3%) in Portugal.[11-17]

The wide variation in the prevalence in various studies is very misleading. To merely read the prevalence figures and interpret the susceptibility of the diabetic population to DR is very simplistic. Quantitative accuracy can be improved by scientific sampling techniques, evaluating heterogeneous subgroups in the population and ensuring quality control of reported finding.

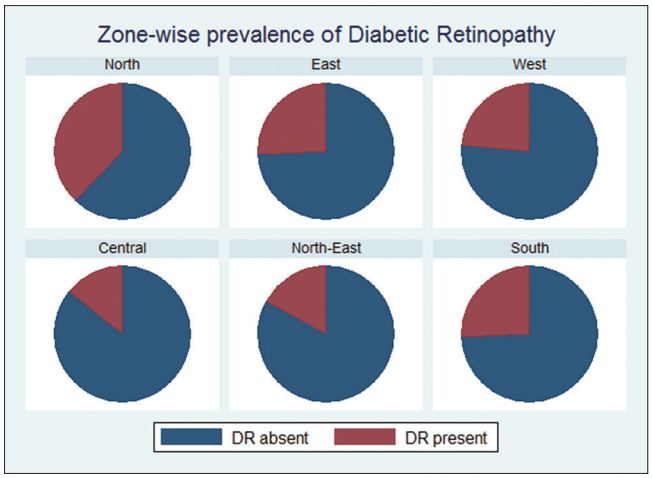

Figure 4: Pie chart showing zone-wise prevalence of diabetic retinopathy

While calculating the average prevalence over many centers, most studies including ours had not taken into consideration the number they actually represented – a correct value would only be obtained using the statistical concept of weighted averages or using cluster sampling in general population.

In our project as well as those conducted by other ophthalmic centers, it was not possible to differentiate in the self-reported data set: Between Type 2 and Type 1 diabetics. The studies with access to all medical records of the patient were able to differentiate between those with Type 1 versus Type 2 diabetes. A wide difference in the prevalence has been found to exist between the two subsets. The prevalence of any DR in those with Type 1 diabetes was 56.0%, and in Type 2 diabetes was 30.3% according to the UK National diabetic retinopathy screening service.[18]

The majority of patients in this study underwent retinal examinations by a clinician; photographic documentation was done in only 15%. Photographic documentation is the standard practice in the National Diabetic Retinopathy Screening Service, UK, and the Joslin retina network, USA. Reported benefits of retinal fundus imaging (photography) are that they allow better standardization, permanent documentation, and accurate reporting by a reading center; and drawbacks are costs of image acquisition and transmission technologies. Low-cost solutions such as the portable battery operated retinal camera coupled with smart phone, using existing cellular networks for transmission, are effective, as demonstrated by Gadkari *et al*.[19] While this solves the issues around image capture and transmission, other issues of reading, grading, reporting, and providing advice to patients, and crucially the uptake and utilization of available care in a timely manner remain.

Prevalence provides a cross-sectional snapshot of morbidity at that point or period. Studies have shown that as the duration of diabetes increases so does the chance of developing DR.

Table 7: Evidence base for prevalence of diabetic retinopathy in India

	Title	Source	Objective	Subjects	Prevalence (%)
Study 1	DR at the time of diagnosis of noninsulin dependent diabetes Mellitus (NIDDM) in South Indian subjects	Rema *et al.* Diabetes Research and clinical practice 34 (1996) Page: 29-36	To evaluate the prevalence of retinopathy at diagnosis of DM in South Indian NIDDM and to make an estimate of the duration of undiagnosed DM	1000	24
Study 2	Population-based assessment of diabetic retinopathy in an urban population in southern India	Dandona *et al.* Br J Ophthalmol 1999, 83:937-940	To assess the prevalence of diabetic retinopathy and the visual impairment caused by it in an urban population in southern India in order to determine its public health significance	2532	22.4
Study 3	Title of the study Prevalence of retinopathy at diagnosis among type 2 diabetic patients attending a diabetic center in south India	Rema *et al.*, Ophthalmol 2000; 84: 1058-1060	To assess the prevalence of retinopathy in newly diagnosed South Indian type 2 diabetic patients attending a diabetic center	448	7.3
Study 4	Title of the study Diabetic retinopathy among self-reported diabetics in southern India: A population-based assessment	V Narendran *et al.* Br J Ophthalmol 2001;86: 1014-1018	To estimate the prevalence of diabetic retinopathy among self-reported diabetics in a population of southern India	54,508	26.2
Study 5	Prevalence of diabetic retinopathy in urban India: The Chennai Urban Rural Epidemiology study (CURES) Eye Study I	Rema *et al.* IOVS, July 2005, Vol. 46, No.:7	To assess the prevalence of diabetic retinopathy in type 2 diabetic subjects in urban India using four field stereo color photography center	1382	17.6
Study 6	Prevalence of and risk factors for diabetic retinopathy in the population of over 30 years of age in Theni district of South India	Namperumalsamy P *et al.* Br J Ophthalmol. 1999 Aug; 83 (8):937-40	To assess the prevalence of diabetic retinopathy in type 2 diabetic subjects in urban India using four field stereo color photography center	80,000 in 53 randomly selected clusters	10.84
Study 7	Prevalence of diabetic retinopathy in India: Sankara Nethralaya Diabetic Retinopathy Epidemiology and Molecular Genetics Study report 2	Raman R *et al.* Ophthalmology. 2009 Feb; 116 (2):311-8	Aim of the study was to estimate the prevalence of diabetic retinopathy in an urban Indian population older than 40 years	5999	18

NIDDM: Noninsulin-dependent diabetes mellitus

With a chronic disease like diabetes, new cases get added to the pool every passing year and they remain within the prevalence pool for the remainder of their lives. Hence, we are confronted by the classical epidemiological fallacy. Does one conclude that a low prevalence is better than a high prevalence? The epidemiological fallacy may be illustrated from the seminal Framingham Heart Study (at the end of 20 years would there be more patients suffering from acute myocardial infarct (AMI) among smokers or nonsmokers?), where paradoxically more nonsmokers developed AMI than smokers. The risk of developing AMI was similar for both groups, but a larger percentage of smokers had passed away earlier, hence were no longer available to be sampled at 20 years. Patients with better access to medical treatment for DM live longer, hence have higher chance of DR and living with it: Adding to the prevalence. In Ethiopia, Alemu *et al*. illustrated this point by demonstrating that urban dwellers had a significantly higher prevalence of retinopathy compared to rural patients, 16.1% and 5.0%, respectively (OR 2.9, $P < 0.02$, after adjustment for duration, age, gender, and hypertension).[20] In developed economies with better health coverage, the prevalence was higher.

As did other studies, this study showed a significantly higher prevalence with increase in age (OR: 2.367) and duration of diabetes (OR: 3.318). In the Wisconsin epidemiological study, prevalence of DR varied from 28.8% in persons who had diabetes for <5 years to 77.8% in persons who had diabetes for 15 or more years.[21] In our series, it varied between 9.23% in freshly diagnosed diabetics <6 months and 35.12% at >5 years. Like in many other studies, males (OR: 1.212) were more affected. The issues of gender bias and social barriers to treatment are known to exist, modifying access to screening and treatment.

Although all relevant medical records were not available for analysis, this study echoes findings of other reported studies with respect to insulin use. In India, 80% of patients seek treatment outside the public sector from private ophthalmologists and NGO hospitals, facilities that have no access to detailed medical records for individuals along the continuum of care they receive for diabetes. In our study, insulin users were predominantly those with Type 2 diabetes, who have a more severe DM and an undefined group of Type 1 diabetics; both groups having a higher chance of developing DR ($P = 0.001$). Like in other series, patients with renal disease were more likely to have DR (OR: 2.633).[22] Patients in our series had more chance of having DR (OR 1.502) if they had suffered from a vascular accident in the form of an AMI or a cerebrovascular accident.[22,23]

An important message to emerge from this study was that vision is not always impaired even in the presence of clinically detectable DR; 22.18% with a visual acuity of 6/18 or better had DR, reinforcing the relevance of annual retinal or comprehensive eye examinations for all persons with diabetes. The cost of managing diabetes can be a major burden for many Indians.

The guidelines issued by the vision 2020 and developed by Aravind eye care system had estimated prevalence for DM 4% and DR 11% in all cases of DM for all states in India for 2007. The values from the present study probably signify a shift upward in DR prevalence although this could also be explained by selection bias since the study reported here was hospital-based, not population-based. This is a reflection of a real rising trend in prevalence, it could, along with population growth and increased prevalence of DM, would further increase the burden of disease computed in 2007.[3]

This was the first time that the national professional association of eye surgeons in India - AIOS had undertaken such an exercise, and the limitations of this study are recognized. These include the sampling methodology contributing to selection bias, and a significant amount of missing data though a standard operating procedure had been put in place it unfortunately was not universally followed due to lack of monitoring and validation mechanism, resulting in missing data. (17.49% of respondents did not fill the form completely), and the length of the form may have contributed to information bias. Dependence on self-reported diabetes, a problem with most similar studies, with lack of information of the Type (1 or 2) of DM was an area of compromise in complete definition of an important variable. Also, no assessment of interobserver variability in assessment or agreement between the various examiners was made.

The AIOS DR eye screening study 2014 reiterated the findings of earlier regional studies on a pan Indian scale. The variability in the data across the zones implied a variation in the access to healthcare facilities. The study also demonstrated the presence of DR despite vision being near normal strengthens a case for regular comprehensive eye examinations for persons with diabetes.

Future such eye screening studies will be more factual in terms of the information gleaned by the implementation of scientific sampling techniques, strict adherence to complete completion of standardized data entry forms along with better verification of the patients diabetic status and biochemistry.

Conclusion

The study reiterated the fi ndings of earlier regional studies on a pan Indian scale and put data in perspective.

Acknowledgment

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Nil.

Conflicts of interest

There are no conflicts of interest.

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